A: SLE patient with renal participation, nephrotic syndrome, very severe symptomology. B: SLE-patient with renal participation, severe symptomology, proliferating type IVa glomerulonephritis. Explanations in the text.

## Claims

- 1. ELISA kits for detecting procollagenase 3 and activated collagenase 3 in body fluids, especially in human serum and synovial fluid, and in cell culture supernatants, comprising at least the following separately packed elements:
  - a) a solid carrier having monoclonal antibodies which are bound thereto and sensitively and specifically bind human procollagenase 3 or activated collagenase 3;
  - b) human recombinant procollagenase 3 or activated collagenase 3 as a standard for the quantitative determination of this enzyme in body fluids;
  - a buffer for producing a standard series of the recombinant procollagenase 3 or activated collagenase 3;
  - d) a buffer for diluting the samples to be analyzed;
  - e) a detectably marked conjugate that binds to collagenase 3;
  - f) and a substrate that allows the visualization of the detectably marked conjugate.
- 2. The ELISA kit as described in Claim 1, wherein the monoclonal antibodies that are bound to the solid carrier are preferably monoclonal antibodies that are formed of the hybridoma having the deposit number DSM ACC 2572.
- 3. The ELISA kit as described in Claims 1 and 2, wherein a combination of two components is used as the detectably marked conjugate, the first component being a biotinylated antibody that binds to procollagenase 3 or to activated collagenase 3 and the second component being used as a high-polymer streptavidin conjugate that binds to the biotinylated antibody.
- 4. The ELISA kit as described in Claims 1 and 2, wherein a conjugated antibody that binds to collagenase 3 is used as the detectably marked conjugate.
- 5. The ELISA kit as described in Claims 1, 2 and 4, wherein the antibodies that function as the conjugate are monoclonal and/or polyclonal antibodies.
- 6. The ELISA kit as described in Claims 1 to 5, wherein the substances used as conjugates may be conjugated with all standard substances, preferably with:
  - horseradish peroxidase
  - alkaline phosphatase.

- 7. The ELISA kit as described in Claims 1 to 6, wherein the human recombinant collagenase 3 used as the standard was expressed in eukaryotic cells and is present in solution or lyophilizated.
- 8. The ELISA kit as described in Claims 1 to 7, wherein the buffer for diluting the body fluids and cell culture supernatants to be analyzed contains sodium citrate.
- 9. The ELISA kit as described in Claims 1 to 8, wherein microtiter plates or standard protein chip technologies are used as solid carriers.
- 10. Monoclonal antibodies that specifically detect and bind procollagenase 3, these monoclonal antibodies having properties like the monoclonal antibodies from the hybridoma cell line having deposit number DSM ACC 2572.
- 11. The monoclonal antibodies as described in Claim 10, whereby the monoclonal antibodies can be changed in a biochemical or molecular biological manner or synthetically, whereby the antibodies or parts that are unnecessary for the detection of procollagenase 3 are lacking, wholly or in part, or these parts are replaced by others.
- 12. The monoclonal antibodies as described in Claims 10 to 11 that are produced from the hybridoma cell line having the deposit number DSM ACC 2572.
- 13. Hybridoma cell line having the deposit number DSM ACC 2572
- 14. Monoclonal antibodies that detect and bind activated collagenase 3 in a specific and sensitive manner, these antibodies having no affinity for procollagenase.
- 15. The monoclonal antibodies as described in Claim 10, whereby the monoclonal antibodies can be changed in a biochemical or molecular biological manner or synthetically, whereby the antibodies or parts that are unnecessary for the detection of activated collagenase 3 are lacking, wholly or in part, or these parts are replaced by others.
- 16. The use of collagenase as a serological marker for diagnostics and especially for monitoring the course of inflammatory rheumatic diseases, especially rheumatoid arthritis.
- 17. The use of collagenase 3 as a serological marker for diagnosis and in particular for monitoring the course of systemic lupus erythematosus, especially for the developmental prognosis when there is tissue proliferation (tumor formation).
- 18. The use of collagenase 3 as a serological marker for diagnosis and for monitoring of the course of other tumorous diseases, especially mammary carcinomas and colorectal carcinomas.
- 19. The use of collagenase 3 as a serological marker for diagnosis and monitoring of the course of other diseases in which an increase of collagenase 3 is described in the scientific literature.